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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,197	10/26/2001	Martin J. Wensley	0208.00014.01R	1701

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EXAMINER	
EREZO, DARWIN P	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
01/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/057,197	WENSLEY ET AL.	
	Examiner	Art Unit	
	Darwin P. Erezo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48,124-130,184-191,198,199 and 204-229* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *124-130 and 211* is/are allowed.

6)☐ Claim(s) *48,184,186-191,198,199,204-210,212-214 and 216-229* is/are rejected.

7)☐ Claim(s) *185 and 215* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 12/24/08.

Terminal Disclaimer

2. The terminal disclaimer filed on 12/24/08 disclaiming the terminal portion of any patent granted on this application has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Amendment

3. The applicant's submission of a terminal disclaimer has overcome the rejections cited in the Final Office action mailed on 10/24/08. Therefore, the rejections have been withdrawn. However, a new grounds of rejection is now provided below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 48, 184, 188, 191, 198, 199, 206, 208, 209, 213, 214, 218, 221-223, 226, 228, 229 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,168,866 to Montgomery.

Montgomery teaches a method of generating an aerosol comprising the steps of heating a physiologically active compound via heaters **20** to vaporize the compound deposited in the chamber **12**; cooling the resulting vapor by mixing the vapor with a

carrier gas coming from carrier gas inlet **2** (the carrier gas is not heated and will inherently cool the vapors) in a predetermined ratio (one liter per minute, col. 3, ll. 11; producing vapors at 22°C, col. 3, ll. 15) to form an aerosol comprised of particles within a desired size range when a stable concentration of particles is reached. Note that the recited claims do not specify the desired size range or what is viewed as a stable concentration. Therefore, the examiner is interpreting the aerosol produced by the Montgomery's device as having a "desired size" when a stable concentration of particles is reached (by having constant heating temperature and flow rate).

It is also noted that Montgomery discloses the step of depositing a coating comprising the compound onto the substrate/chamber **12** prior to turning on the heater; wherein the carrier gas is a breathable gas (air); wherein the carrier gas passes across the surface of the compound in the chamber; wherein the aerosol is delivered to a patient.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 186, 189, 204, 216, 219, 224 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of US 5,894,841 to Voges.

(claims 186, 204, 216, 224) Montgomery discloses all the limitations of the claim except for the particle size. However, Voges discloses that particle sizes in the range of about 1-3 microns is the preferred size for respiratory treatment (col. 5, lines 3-4 of Voges). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the particle size in the range of about 1-3 microns because such particle size is usable for respiratory treatments.

(claims 189, 219) Montgomery discloses all the limitations of the claim except for the cited compounds. However, Voges discloses nicotine to be a desired vaporized compound (col. 3, line 2 of Voges). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vaporize any volatile compound in the device of Montgomery, including nicotine, since the use of a specific compound is merely dependent upon the intended therapy.

9. Claims 187, 205, 217, 225 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 5,874,841 to Weers et al.

The above combination of Montgomery/Voges is silent with regards to the particle size in the range of 10 nm to 100 nm. Weers teaches that is known in the respiratory art to have particle sizes in the range of 10 nm to 100 nm (col. 5, line 6).

Therefore, it would have been obvious to one of ordinary art at the time the invention was made to modify the steps taught by the above combination to include the particle size range of 10 to 100 nm since Weers teaches that the recited range is known in the art and would be dependent upon the intended therapy.

10. Claims 190, 207, 210,212, 220, 227 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery.

(claims 190, 207, 220, 227) The above combination discloses the claimed invention except for the recited range of time. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

(claim 210,212) The above combination discloses the claimed invention except for the recited concentration. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited concentration since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Allowable Subject Matter

11. Claims 124-130 and 211 are allowed.

12. Claims 185, 215 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773